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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/411,075	10/04/1999	PRAMOD K. SRIVASTAVA	8449-054-999	7824

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PENNIE & EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
1636	23

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/411,075

Applicant(s)

SRIVASTAVA, PRAMOD K.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51,55-59,63-71 and 77-121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 56,58,59,63-66,79-92,99-102 and 112-115 is/are allowed.
- 6) ☒ Claim(s) 51,67,69-71,77,78,93-98,103 and 107-111 is/are rejected.
- 7) ☒ Claim(s) 55,57,68,104-106 and 116-121 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of a reply, filed April 1, 2003 as Paper No. 22, to the previous Office Action. Amendments were made to the claims. Specifically, Claim 60 was cancelled and new claims 112-121.

Claims 51, 55-59, 63-71 and 77-121 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 21, mailed August 26, 2002, that is not addressed in this action has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 69-71, 93-98 and 107-109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection not necessitated by amendment.**

Specifically, claims 69-71, 93-98 and 107-109 recite limitations wherein the molecule that is identified is useful for the treatment of various diseases (e.g., cancer, infectious disease, etc.). There is no indication in the claim that the molecule identified would necessarily result in the treatment of any of these diseases in humans, therefore the claim is indefinite. Addition of the term "potentially" prior to "useful in the preamble of the claim would be remedial.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51, 67, 77, 78, 103, 110 and 111 are rejected under 35 U.S.C. 102(b) as being anticipated by Erickson et al. (US Patent No. 5,525,490; see entire document; henceforth Erickson). **This is a new rejection not necessitated by amendment.**

In order to clarify how Erickson applies as art to the aforementioned claims, the examiner wishes to indicate the following as definitions provided by the instant specification: a heat shock protein receptor (HSPR) is defined on page 10, line 33 to page 11, line 3 as a receptor for any heat shock protein family member which binds to a heat shock protein (HSP); on page 14, lines 1-2, the specification indicates that an HSPR encompasses fragments thereof; on page 15, lines 12-13, the specification describes HSPR positive cells as those cells that express an HSPR.

Erickson discloses a reverse two-hybrid method as a screening assay for identifying small molecule inhibitors of protein-protein interactions (see for example column 15, lines 31-34). A specific example is given wherein small molecules inhibitors (such as estradiol) are sought for the disruption of the interaction between HSP90 (a heat shock protein) and the hormone binding domain of the estrogen receptor (see for example column 15, lines 38-52). The hormone binding domain of the estrogen receptor is deemed an HSPR because it fits the definition set forth in the specification; it is a fragment of a receptor that has the capacity to bind a heat shock protein. The cells in which the assay takes place are deemed to be HSPR positive cells because they express

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what is characterized as an HSPR. Furthermore, these cells are purified away from HSPR negative cells by virtue of the biological selection process to obtain a yeast strain that expresses the HSPR; for example a nutritional marker located on the plasmid that expresses the HSPR will complement a nutritional defect in a particular yeast strain, allowing only the cells that express the HSPR to grow under specific conditions, thereby purifying the HSPR positive cells away from the HSPR negative cells by a "life or death" purification process. Finally, Erickson teaches that the screening method/reverse two-hybrid method involves the screening of potential inhibitors for the intermolecular binding of two interacting polypeptides (such as HSP90 and the HSPR) by screening agent banks which include compound libraries and peptide expression libraries (see for example column 10, lines 9-16). Erickson even contemplates that these agents can serve as potential therapeutic agents, although Erickson does not describe testing these compounds in non-human animals. Therefore, Erickson teaches all of the elements set forth in the rejected claims 51, 67, 77, 78, 103, 110 and 111 in view of the definitions set forth in the instant specification.

Allowable Subject Matter

Claims 51, 67, 77, 78, 103, 110 and 111 are rejected in view of the prior art.

Claims 69-71, 93-98 and 107-109 are rejected as being indefinite.

Claims 55, 57, 68, 104-106 and 116-121 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 56, 58, 59, 63-66, 79-92, 99-102 and 112-115 are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
June 24, 2003

DAVID GUZO
PRIMARY EXAMINER
